BQC-93-043

Date: July 19, 1993 BQC-93-043

To: End Stage Renal Disease Agencies ESRD <u>3</u>

From: Susan Wood, Deputy Director

Bureau of Quality Compliance

Subject: Alert on Appropriate Bacteriologic Culturing of Water in End Stage Renal Disease

(ESRD) Dialysis Facilities

Attached is a copy of Regional Program Letter No. 93-40 from the Health Care Financing Administration Region V, Division of Health Standards and Quality. This letter alerts ESRD facilities to the appropriate protocols that should be used for bacteriologic culturing of the water used in dialyzer processing. This information will be shared with our surveyor staff who are involved in reuse and CLIA surveys.

Please share this information with appropriate staff and laboratories used by your agency for this work. Please direct questions to Stephen D. Schlough, Chief, Hospital and Health Services Section, Bureau of Quality Compliance at the indicated above address or telephone him at (608) 266-3878.

Attachment

cc: -BQC Staff

- -Office of Legal Counsel
- -Ann Haney, DOH Admin.
- -Kevin Piper, BHCF Dir.
- -HCFA, Region V
- -Illinois State Agency
- -Ohio State Agency
- -Michigan State Agency
- -Indiana State Agency
- -Minnesota State Agency
- -Commission on Geriatric Health
- -WI Hospital Association
- -Non-LTC BQC Memo Subscribers
- -Secy, Dept. of Reg. & Licensing
- -Renal Dialysis Network 11

Department of Health & Human Services Health Care Financing Administration Region V 105 West Adams Street 15th Floor Chicago, Illinois 60603-6201

June 1993

Refer to: CR5

Division of Health Standards and Quality Regional Program Letter No. 93-40

Subject: ALERT on Appropriate Bacteriologic Culturing of Water in End Stage Renal Disease (ESRD)

Dialysis Facilities

The subject of this program letter is to request you <u>alert your ESRD</u> and <u>CLIA surveyors</u> to the appropriate protocols for bateriologic culturing of the water used in dialyzer reprocessing. This information should be of use during the focused reuse surveys of ESRD facilities and may be of use during your CLIA surveys.

Recently, a State agency surveyor found that a Community Dialysis Center was using a laboratory that used blood agar culture medium for the spread plate assay technique, rather than plain trypticase soy agar (TSA). In addressing this problem, the surveyor talked with clinical support staff of the corporate facility chain, the laboratory that performs the water culture testing for the chain, and a staff member of the Centers for Disease Control and Prevention (CDC).

The laboratory, Damon Laboratory, after consulting with a staff member of the CDC, agreed to change the culture medium for the spread plate assay technique for all of the testing which it does for Community Dialysis Center facilities. We and the CDC want to ensure that the plain TSA culture medium is used nationwide for this specific assay procedure.

The CDC provided the following information: The dialysis facility should be knowledgeable of the specific culturing techniques and procedures employed by the laboratory it uses, if any. In interviewing the facility or, if necessary, by telephone contact with the outside laboratory, it is important to determine that the laboratory is performing the assays appropriately. **Bacteriologic culturing of water** used in dialyzer reprocessing should be done **at least monthly**.

The cultures must be incubated at 37 degrees celsius for 48 hours regardless of which culture medium is used (i.e., membrane filtration, commercial water testers, or spread plate). If the spread plate technique is used, the culture medium should not be blood agar, but rather plain TSA without blood. A 0.1-0.5 mL of the water sample should be placed on the TSA plate using a pipette. A calibrated loop should not be used. If these procedures are not followed, sensitivity of the assay may be decreased dramatically.

If you have any questions, please contact Gwendolyn Michel at 312/886-5211 for Indiana, Michigan and Ohio or Sally Jo Wieling at 312/353-8853 for Illinois Minnesota and Wisconsin or Norma Stallworth, ESRD Nurse Consultant at 312/353-8853.

/s/ Sally Jo Wieling for Charles Bennett Branch Chief Survey and Certification Review Branch Division of Health Standards and Quality